disease activity and lab measurements. **RESULTS:** 106 papers met our inclusion criteria. Studies were published between 2003 and 2015 and mostly from Europe; 39 included patients starting etanercept, 36 included patients starting rituximab and 32 patients starting tocilizumab. Mean age ranged between 42.9 and 63.3 years, 78.2% were female. The drugs were given in combination with methotrexate and/or other traditional DMARDs in over two thirds of the studies. Mean disease duration varied between 4 and 17.5 years, baseline disease activity 28 scores between 4.3 and 7.0, and baseline health assessment questionnaire values between 1 and 2.9. The mean percentage of rheumatoid-factor positive patients was 76.4%. Reporting of comorbidities and smoking status was generally poor, with only few studies providing detailed data. **CONCLUSIONS:** This systematic review of data from observational studies and clinical databases indicates that the characteristics of RA patients starting biological DMARDs outside clinical trials in the real world varied widely. These observational data will now be compared with clinical trial data but it seems likely that some patient groups were not well represented in the trials.

PMS136

EFFECTIVENESS OF A REFERRAL PROGRAM FOR EARLY ARTHRITIS DIAGNOSIS AT PRIMARY CARE CENTERS IN PORTUGAL - PRELIMINARY RESULTS FROM THE SIARA STUDY

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OBJECTIVES: Early diagnosis and treatment of inflammatory arthritis can limit the impact of disease outcomes. We aimed to evaluate the effectiveness of a referral program on the identification of patients with suspected inflammatory arthritis. **METHODS:** SIARA (Referral Strategies and Disease Education Impact on Diagnosis and Referral of Axial Spondyloarthritis and Rheumatoid Arthritis Patients) is an observational prospective, randomized (by clusters of primary care centers) study to analyze the impact of Referral Support Actions (RSA) consisting of physician educational sessions about the disease and implementation of referral recommendations. The participating primary care centers (n=24) were randomly assigned to RSA or control group (with no intervention). Both RSA and control groups identified and referred patients with suspected inflammatory arthritis to the rheumatology unit of the reference hospital (n=6). The main studied outcome is the correct diagnosis of inflammatory arthritis / rheumatoid arthritis confirmed by the rheumatologist of the reference hospital. **RESULTS:** A total of 125 patients were referred to a rheumatologist (considering 4 hospitals): 61 RSA patients and 64 control patients. Mean age was 48.9 years (range: 19-73) and 88.8% were female (differences not statistically significant between groups). About 14.8% (n=9) of RSA patients and 4.7% (n=3) of controls had a confirmed diagnosis of arthritis (any type) by the rheumatologist (OR=3.5; 95%CI, 0.9-13.7; Chi-square p=0.056). Rate of confirmed rheumatoid arthritis was 4.9% in RSA patients and 1.6% in controls (p=0.287). The majority of the patients (82.0%) were referred in the 4 months after educational session (month 3:63.9%; month 6:96.7%). **CONCLUSIONS:** Although the study results still lack statistical significance, this preliminary data already suggests a positive impact of a referral program on the early identification of inflammatory arthritis, especially after the first few months. This should be further analyzed and considered by healthcare deciders in order to improve health outcomes in inflammatory arthritis.

PMS137

A WEB-BASED SURVEY TO INVESTIGATE THE EXTENT OF AWARENESS AND UNDERSTANDING FOR BIOSIMILAR AMONG JAPANESE PHYSICIANS AND PHARMACISTS

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OBJECTIVES: Several biosimilar products have been developed and marketed in Japan. However, the degree of understanding of biosimilars among healthcare professionals is uncertain. The objective of this study was to investigate the extent of awareness and understanding of biosimilars among Japanese physicians and pharmacists. **METHODS:** This was a non-interventional, web-based survey conducted in May 2015. Japanese physicians (rheumatologists/oncologists) and pharmacists voluntarily participated and provided their thoughts via questionnaires. Rheumatologists who have seen >= 30 rheumatoid arthritis patients/month on average and have prescribed biologics (Remicade/Humira, etc.) to at least one patient, and oncologists who have seen >= 30 cancer patients/year with use of biologics (Rituxan/Avastin/Herceptin, etc.) to at least one patient were eligible. **RESULTS:** Of screened physicians, about 35% have never heard of "biosimilar", whereas 96% of pharmacists were aware of "biosimilar". One hundred rheumatologists, 120 oncologists (30 each for Hematology/Breast/Gastroenterology/Respiratory) and 90 pharmacists who met the criteria and were aware of biosimilar were analyzed for a further questionnaire. 73% of rheumatologists and 82% of oncologists recognized that biosimilars "are relatively less expensive" and 62% of physicians simply answered "subsequent product/generic". 58% of rheumatologists showed an intention to prescribe future biosimilars, whereas 73% of oncologists showed prescription intention. The main reason behind this was "reduction of burden on patients", followed by "confirmed similarity in efficacy/safety". Physicians with little intention to prescribe biosimilars showed strong concerns for similarity to the innovator (>70%) and insufficient clinical data in efficacy/safety perspectives. Similarities in clinical efficacy/safety were more emphasized compared to structural and functional similarities in biosimilar development pathways. **CONCLUSIONS:** Awareness of biosimilars amongst Japanese physicians was still low with a strong leaning toward burden on patients and sufficient clinical data to confirm the similarity. Providing learning opportunities for general tenets of biosimilarity and its development pathways are vital to increase public recognition of biosimilars.

PMS138

ASSESSMENT OF RISK SHARING AGREEMENTS (RSAS) IN SELECT GLOBAL MARKETS WITH SPECIFIC FOCUS ON ACTIVITIES SURROUNDING IMMUNOMODULATORS

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OBJECTIVES: To understand current Risk Sharing Agreements (RSAs) for immunomodulators for rheumatoid arthritis, psoriasis, and psoriatic arthritis in 11 markets aimed to optimize specific RSA strategies/ payer partnerships. **METHODS:** Review of publicly available health authority websites and peer-reviewed journals. Interviews with payers and stakeholders who influence RSA decisions and ex-pharma executives for validation and gap filling. **RESULTS:** USA manufacturers negotiate RSAs with private health insurers and states. Payers in USA integrate financial risks with manufacturers using outcome based agreements (OBAs). Canada established RSAs with Provinces and use financial based agreements (FBAs) but some are OBAs. France requires volume based FBAs for new high-priced therapies to limit budget impact. Germany uses FBAs at the sickness fund level rather than the Gemeinsamer Bundesausschuss (G-BA) level because sickness funds manage their own budgets. Some OBAs exist with clearly defined outcomes. Italy negotiates RSAs at the national level for new therapies entering the market ranging from FBAs to OBAs depending on the specific therapy and target patient population. Italy may also require manufacturers to incorporate drug monitoring registries in the RSA. In Spain performance based OBAs are used for new therapies with nominal additional benefit at the regional level with clearly established outcomes. Netherlands and Sweden use evidence development (CED) agreements for high priced products to generate cost effectiveness data. In Switzerland, RSAs are new and mostly FBAs and mainly for orphan disease therapies and off-label indications with price capping. In the UK,FBAs with few OBAs are used affecting product price but are not rebate based. Australian RSAs are mostly FBAs and are referred to as "Deeds of Agreement." **CONCLUSIONS:** With high-cost immunomodulators, authorities are shifting towards integrating RSAs in price negotiations to optimize budget expectations prior to launch. Europe prefers FBAs to OBAs which often require clearly defined outcomes.

SYSTEMIC DISORDERS/CONDITIONS – Clinical Outcomes Studies

PSY1

ASSOCIATION OF ADVERSE EVENTS AND HEALTH SERVICE USAGE WITH TAPENTADOL PROLONGED-RELEASE TREATMENT COMPARED WITH MORPHINE CONTROLLED-RELEASE (CR) AND OXYCODONE CR: A UK PRIMARY CARE OBSERVATIONAL STUDY

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OBJECTIVES: This study compared adverse outcomes and resource use in patients treated with tapentadol prolonged-release (PR) with those treated with morphine controlled-release (CR) and oxycodone CR. **METHODS:** Data were from the Clinical Practice Research Datalink, a database derived from UK primary-care. Patients prescribed tapentadol PR between May 2011 and December 2014 were matched to two groups of controls treated with either morphine CR or oxycodone CR on gender, age, pain duration, pain site and aetiology, Charlson index and prior analgesia. Rates of adverse events (constipation and nausea/vomiting) were compared by adjusted hazard ratio (aHR). Rates of primary-care contacts, accident and emergency contacts, outpatient clinic letters and, for a subset of patients linked to Hospital Episode Statistics (HES), inpatient admissions were compared using incident rate ratios (IRRs) derived from Poisson regression. **RESULTS:** 1,176 patients prescribed tapentadol PR were identified; 1,103 (93.8%) had a pain diagnosis. Of these 789 (67.1%) were matched to morphine controls and 557 (47.4%) to oxycodone controls. Compared with controls, adverse events with tapentadol PR treatment were reduced: aHR=0.643 (95% CI 0.459–0.901; p=0.010) versus morphine CR and 0.505 (0.335–0.763; p=0.001) versus oxycodone CR. Compared with morphine CR, primary-care contacts (IRR=0.817; 0.786–0.850), accident and emergency attendance (0.699; 0.560–0.870) and outpatient letters (0.715; 0.543–0.939) were also reduced. For oxycodone CR, the respective figures were 0.776 (0.706–0.840), 0.840 (0.639–1.103) and 0.545 (0.400–0.739). For the subset of HES-linked patients the rates of inpatient admissions were 0.723 (0.590–0.884) and 0.458 (0.357–0.585) vs. morphine CR and oxycodone CR, respectively. **CONCLUSIONS:** Tapentadol PR was associated with significantly fewer adverse gastrointestinal events than morphine CR or oxycodone CR. There was also significantly reduced primary- and secondary-care resource use. As with all observational studies, potential bias due to residual confounding and confounding by indication should be considered.

PSY2

CLINICAL AND ECONOMIC BURDEN OF PULMONARY EXCERBATIONS IN PATIENTS WITH CYSTIC FIBROSIS WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION

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OBJECTIVES: To assess the clinical and economic burden of pulmonary exacerbations (PEx) in patients with cystic fibrosis (CF) and homozygous for the F508del CFTR gene mutation. **METHODS:** Medical chart data from patients with CF ≥12 years old were collected in France, Germany, Italy, Spain, Australia and Canada. Demographics, clinical characteristics, and selected resource utilization were obtained for a 12-month baseline period and a follow-up period ranging from 2-36 months. The frequency of PEx and associated resource utilization was assessed overall and by age (12-17, ≥18 years) and lung function (percent predicted forced expiratory volume in 1-second [ppFEV1] ≥70%, 41-69%, ≤40%). Descriptive analyses were conducted. **RESULTS:** Data for 523 patients were included. Baseline mean ± SD age was 24.8 ± 9.5 years and mean ± SD ppFEV1 was 67.1 ± 22.9%. During

the 12-month baseline period, 26% of patients experienced 1 PEx, 15% had 2, and 20% had ≥3. Corresponding proportions over a mean of 27 months of follow-up were 16%, 12%, and 52%. The mean PEx rate rose from 1.3 to 1.6/patient-year from baseline to follow-up. In the follow-up period, proportions of patients with at least 1 PEx and rates of PEx were higher among adults (84%; 1.7/patient-year) versus adolescents (70%; 1.5/patient-year) and for patients in the severe ppFEV1 group (86%; 2.0/patient-year) compared with the mild group (70%; 1.1/patient-year). Among patients with PEx, 61% required inpatient hospitalization (mean ± SD length of stay, 13.3 ± 7.4 days) and 73% required either hospitalization or IV antibiotics. **CONCLUSIONS:** The majority of patients with CF homozygous for the F508del CFTR gene mutation experience at least one PEx annually and many PEx are associated with lengthy hospitalizations. The rates of PEx increase over time and are highest for adults and for those in the most severe lung function group, consistent with a progressive disease.

PSY3

EFFICACY OF THE MICA ANTIBODY FOR TRANSPLANT PATIENTS

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OBJECTIVES: MICA antibody identification is a test performed on transplant patients to check for the presence of donor-specific MICA for the purpose of predicting the incidence of organ rejection among transplant patients. The purpose of this assessment was to evaluate the effectiveness. **METHODS:** The literature search was performed using 8domestic research databases and 3core databases. A total of 9papers that remained. Each of the stages from literature search to application of selection criteria and data extraction was independently by 2researcher. The SIGN was used for the quality assessment. **RESULTS:** There were 5studies reporting on the medical results of kidney transplant patients. 2of the studies reported no significant differences in the graft survival rate and incidence of organ rejection(p=.67). There were 3studies reporting of heart transplant patients. There was one study reporting of lung transplant patients. The incidence of organ rejection was reported to be 42.0%(p=ns). **CONCLUSIONS:** MICA Identification lacked clinical effectiveness for the following reasons: i)there were no significant differences in the graft survival rate and incidence of organ rejection; ii)it is difficult to determine whether the different results for the graft survival rate and incidence of organ rejection reported.

PSY4

A SYSTEMATIC LITERATURE REVIEW AND NETWORK META-ANALYSIS OF CAPSAICIN 8% PATCH VERSUS ORAL NEUROPATHIC PAIN MEDICATIONS FOR THE TREATMENT OF PAINFUL DIABETIC PERIPHERAL NEUROPATHY

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OBJECTIVES: The efficacy and safety of capsaicin 8% patch (Qutenza) for treating painful diabetic peripheral neuropathy (PDPN) has recently been studied but direct comparison with other treatments is lacking. The objective was to obtain estimates of the relative efficacy and safety of oral treatments for PDPN and capsaicin 8% patch. **METHODS:** A systematic literature review (SLR) and network meta-analysis (NMA) were conducted. The SLR collated data from all published randomized controlled trials (RCTs) comparing either pregabalin, duloxetine, amitryptiline or gabapentin. Efficacy data for capsaicin 8% patch was obtained from 12-week placebo-controlled RCT (STEP) and a 12-month open-label randomized study versus standard of care (PACE). Electronic databases (Embase, Medline, CRD-Dare and Cochrane) were searched up to February 2014. Search results were screened, eligible studies were assessed for risk of bias and data were extracted. Efficacy outcomes selected for Bayesian NMA (WinBUGS v.1.4) included responder status (≥30%/ ≥50% reduction in pain) and absolute change in pain score from baseline. Safety endpoints included nausea, diarrhoea, somnolence and dizziness. **RESULTS:** Out of the 400 unique records identified, 24 were eligible for inclusion in the review. Eight studies were included in the NMA for ≥30% pain reduction, 10 for ≥50% pain reduction, and 11 reporting pain score change. No significant differences were observed between treatments regarding either responder rate based on ≥30%/ ≥50% pain reduction or pain score change from baseline. Scenario analyses considering different dosing regimens of pregabalin and duloxetine, different definitions of clinical endpoints and inclusion of PACE trial data did not significantly change the results. The capsaicin 8% patch exhibited none of the investigated safety events, whereas all orals reported dose-dependent side-effects. **CONCLUSIONS:** This NMA found that capsaicin 8% patch, pregabalin, duloxetine, and gabapentin do not have different efficacy profiles for PDPN; however, capsaicin 8% patch exhibits fewer systemic adverse events.

PSY5

HOW ARE PAIN TREATMENT RESPONSE RATES IN PRIMARY CARE INFLUENCED BY CO-PRESCRIPTION OF CYP2D6 INHIBITORS?

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OBJECTIVES: To determine the rates of co-prescription of CYP2D6-inhibiting medications with pain medication and the impact on response rates to pain medications, in the UK primary care setting. **METHODS:** Codeine and tramadol are prodrugs requiring activation by the CYP2D6 enzyme. These drugs may have limited effectiveness when co-prescribed with other medications known to inhibit the CYP2D6 pathway. This contrasts with CYP2D6-independent analgesia, e.g. buprenorphine, which do not require CYP2D6 activation. We identified the co-prescription of three study pain medications; buprenorphine, codeine and tramadol with CYP2D6-inhibiting drugs including amitriptyline and fluoxetine. Patients aged ≥18 years with chronic non-malignant pain and prescribed buprenorphine, codeine or tramadol between 01/01/2009 and 31/01/2013 were identified in The Health Improvement Network (THIN) database. Patients were excluded if they had history of; chronic kidney disease stage 4/5, cancer, neuropathic pain, sciatica/radiculopathy, diabetes, back pain or a prior prescription for a study drug. Patients were classified as responders if they were either "cured" (discontinued treatment) or stable (remained on treatment), or a non-responder if they were referred to a pain clinic or switched to a CYP2D6-independent analgesic. Multivariate logistic regression was used to identify the predictors of response and estimate the influence of CYP2D6-inhibitors. **RESULTS:** The cohort consisted of 43,632 patients: 90.8% were responders, and CYP2D6-inhibiting drugs were prescribed to 33.8% of the cohort. Almost three times as many patients failed to respond in those prescribed a CYP2D6-inhibitor (16% vs. 6%). Controlling for medication, demographics and co-morbidities the logistic regression indicated the odds of responding for those with a CYP2D6-inhibiting co-prescription were 39% lower than those without a co-prescription for a CYP2D6 inhibiting drug (OR= 0.61, 95% CI 0.57 to 0.66). **CONCLUSIONS:** Chronic non-malignant pain patients with a co-prescription for a CYP2D6-inhibiting medication were significantly less likely to respond to analgesia treatment and therefore received suboptimal pain management.

PSY6

REAL-WORLD EVIDENCE OF IRON CHELATION THERAPY IN TRANSFUSION-DEPENDENT MDS PATIENTS: A PORTUGUESE HOSPITAL REGISTRY

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OBJECTIVES: Transfusional iron overload is common among patients with myelodysplastic syndromes (MDS) receiving red blood cell (RBC) transfusions. Emerging evidence indicates that iron chelation therapy (ICT) could improve health outcomes in MDS patients with low/intermediate-1 IPSS risk. This study aimed to investigate clinical evolution and transfusion dependency of MDS patients under ICT with deferasirox, in clinical practice. **METHODS:** This was a retrospective analysis of a hospital registry of MDS patients followed-up by imunohemotherapy. Longitudinal data records were aggregated in 3 months periods. Exploratory analysis was performed to characterize patients. Generalized Estimation Equation models were used to estimate the effect of time on average ferritin levels and RBC transfusions, controlled by patient's initial conditions and deferasirox dose. Generalized Linear Mixed-effects Models were estimated to assess individualized evolution patterns. In modelling only patients chelated for ≥6 months were considered. **RESULTS:** A total of 877 records of 17 MDS patients (53% male), classified as low risk at diagnosis, were included in the analysis. Median ages at diagnosis, beginning of RBC transfusions and beginning of ICT were 71, 74 and 77, respectively. Patients had received an average of 51.6±26.2 RBC units before ICT. Average values of clinical parameters were calculated for each patient. Sample medians were: ferritin 3674.3ng/mL, hemoglobin 8.2g/dL, alkaline phosphatase 91.3UI/L, gamma-glutamyl transferase 0.4UI/L, aspartate aminotransferase 27.0UI/L, alanine aminotransferase 42.9UI/L and blood creatinine 0.9mg/dL. From the 8 patients chelated ≥6 months: 6 presented a decrease on ferritin levels and 4 presented a decrease in RBC transfusions (one reaching transfusional independence), over time. Marginal models demonstrated that average ferritin levels and number of RBC decrease with time (β=-141.9 p=0.008; β=-0.043 p=0.001, respectively). **CONCLUSIONS:** Analysis of real-world data from a Portuguese registry of transfusion-dependent MDS patients chelated with deferasiforx, for ≥6month, indicated that both ferritin levels and RBC transfusions tend to decrease with time.

PSY7

GUILLAIN-BARRE SYNDROME: CLINICAL PRESENTATION, TREATMENT PATTERN AND OUTCOME

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OBJECTIVES: To study the clinical presentations, treatment pattern and outcome of patients diagnosed with Guillain-Barre Syndrome (GBS). **METHODS:** A retrospective observational study, carried out in a tertiary care teaching hospital. Data of patients diagnosed with GBS and admitted to ICUs, medical wards and neurological wards from 2008 to 2013, was collected from medical records department (MRD) registry using ICD-10 code G61.0 **RESULTS:** During the study period total 130 patients were diagnosed with GBS. The mean age of the study population was 35.3±20.7 years (mean±SD) and 55.4% (n=72) patients were male. Hospital admissions due to GBS showed a marked escalation yearly from 2008 to 2013. 48.4% (n=63) of patients reported flu like syndrome along with loose stools one week prior to GBS onset. The main clinical manifestations of GBS, bilateral ascending weakness and areflexia was seen in 69.2% of patients. Respiratory paralysis is the major cause of mortality in GBS patients and was present in 17.7% (n=23) of the patients. Among the study population 49.2% (n=64) of patients received intravenous Ig (IVIg) therapy and 11.5% (n=15) of patients underwent plasmapheresis. Other supportive therapies included were physiotherapy/occupational therapy (13.8%) and corticosteroid therapy (10.8%). Due to high economic burden 14.6% (n=19) of patients denied all treatments. Among the patients who received IVIg therapy, 4.7% showed complete recovery and 82.8% showed significant improvement whereas patients who received plasmapheresis, 85.7% showed significant improvement. The mortality rate in patients who received IVIg was 1.6% whereas in plasmapheresis was 7.1%. **CONCLUSIONS:** Both IVIg and plasmapheresis treatments showed significant improvement within 3 weeks. In our study setting, IVIg was the preferred treatment option due to low side effect profile and ease of administration however cost of treatment is higher compared to plasmapheresis. Plasmapheresis was associated with complications such as BP, HR fluctuations.